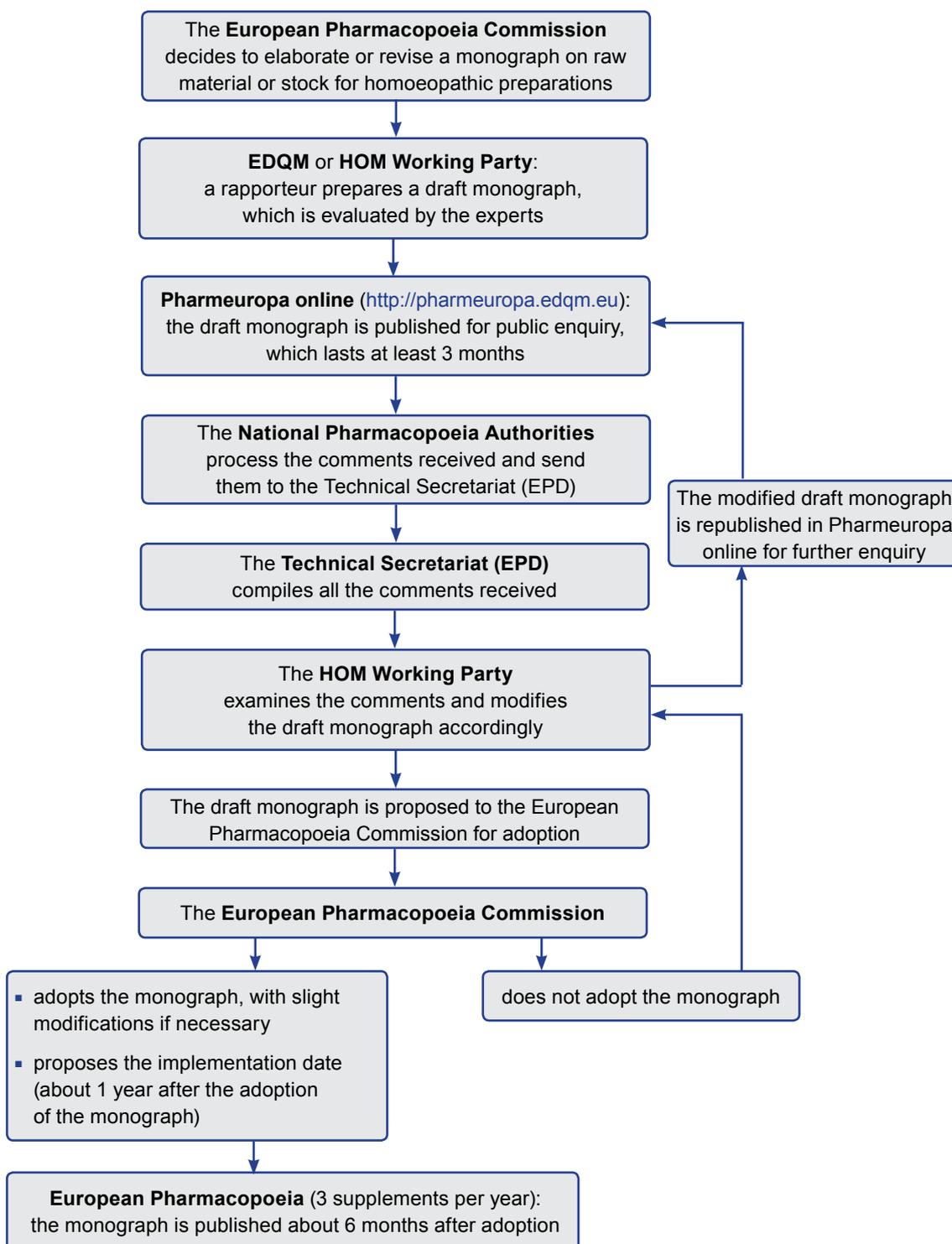


ELABORATE OR REVISE A MONOGRAPH ON RAW MATERIALS OR STOCKS FOR HOMOEOPATHIC PREPARATIONS

Procedure 5

This procedure is similar to Procedure 1 and applies to raw materials or stocks for homoeopathic preparations only.



Adaptation of national monographs on raw materials and stocks for homoeopathic preparations

Procedure No. 5

The procedure applies to monographs on raw materials and stocks for homoeopathic preparations authorised for use in the member states. The work is co-ordinated by the EDQM and overseen by the HOM Working Party.

This procedure is used for the elaboration of monographs that are applicable in all the member states that have signed the European Pharmacopoeia Convention and which are useful for the evaluation of the quality of these substances, in particular in the context of mutual recognition.

Where several official national monographs exist, they can be adapted to produce a European monograph with harmonised requirements. As part of this procedure, tests can be introduced into the European monograph if they assist in guaranteeing the quality of the substance, whether or not they are present in any of the existing national monographs, provided that this is justified and supported by scientific data.

Cultural differences in the area of homoeopathy in Europe sometimes make harmonisation difficult, but a European system can only be established on a common foundation while taking into consideration aspects specific to each country. Undoubtedly, efforts will have to be made at the national level to overcome these difficulties. It should always be kept in mind that the final goal is the quality of raw materials and stocks for homoeopathic preparations and that the purpose of European Pharmacopoeia (Ph. Eur.) monographs is not to exclude substances from the market.

INITIATION OF WORK

1. Survey of the National Authorities to draw up a list of high priority monographs on a national basis.
2. Examination of the list of substances by the HOM Working Party to identify those substances for which national monographs already exist.
3. Circular letter to be sent by the Secretariat to the National Pharmacopoeia Authorities indicating the substances/monographs to be treated by this procedure and asking for the most recent versions of national monographs, their English translations (if they exist), the report(s) of any study performed for the drafting of the national monographs, the validation and/or the performance data for the described methods, any information about manufacturers/suppliers relevant for the elaboration of a monograph, details of problems that have been reported, and whether the monograph is under revision at a national level.
4. The Secretariat sends manufacturers/suppliers of the substance a standard letter informing them of the procedure and the programme to be followed and asking them to:
 - comment on the existing monographs(s);
 - supply current production batches;
 - supply internal specifications as accepted by the competent authority, methods of analysis and validation data;
 - supply batch analysis data for stability batches;
 - if possible, supply a batch that can be subsequently used as a reference standard (CRS/HRS), if required.

PREPARATION OF THE FIRST DRAFT MONOGRAPH

1. Each substance is assigned to a co-ordinator and if necessary a co-worker within the HOM Working Party. The co-ordinator and the co-worker should have a laboratory at their disposal to check the proposed methods, compare existing methods and if necessary develop tests.
2. Where several national monographs exist, the co-ordinator makes sure that they have the same scope. If not, a scope is proposed for the European monograph. In general, it is proposed that the scope of the European monograph should cover the various scopes of the national monographs so that no products will be excluded from the European market if their quality complies with Ph. Eur. requirements. When a common definition cannot be given (closely related starting materials), more than one monograph with the same quality requirements (same methods) may be elaborated.
3. After receiving the requested samples and documentation, the Secretariat sends copies of the documentation and portions of the samples to the co-ordinator and, if necessary, to the co-worker.
4. If necessary, the EDQM Laboratory examines batches, using the methods in the national monograph(s), and gives its opinion on these methods.
5. After receiving the samples and the data, the co-ordinator agrees target dates for completion of the laboratory work (preferably not more than 6 months) and initiates the work required, if necessary, with the manufacturer and the co-worker.
6. The co-worker or, in exceptional cases, the EDQM laboratory carries out the necessary verifications and sends comments to the co-ordinator who informs the Secretariat on progress.
7. The first draft, conforming to the relevant [technical guide](#) and the [Style guide](#) is produced by the co-ordinator, ideally within 3 months after the completion of the laboratory work. This first draft is based on the national monograph(s) and takes account of the results obtained by the laboratory(ies). Where appropriate, CRS/HRS strategy for the monograph is fixed with the EDQM Laboratory. Products currently on the European market should a priori comply with the prescribed requirements.
8. The homoeopathic production methods mentioned in the general monograph *Methods of preparation of homoeopathic stocks and potentisation (2371)* are mentioned in the draft European monograph, and the specifications and characteristics of the product are given separately for each production method.

If a production method mentioned in a national monograph is needed, it is described in full in the draft European monograph.

9. Where a test is prescribed in one national monograph and not in another, the HOM Working Party initiates a discussion on whether or not it is necessary to keep the test, taking the following into consideration:
 - the test is included in the first draft of the European monograph if justified for reasons related to the quality of the substance and if supported by scientific data, as described in the relevant Guide for the elaboration of monographs on homoeopathic preparations;
 - the test is not included if it does not provide an additional guarantee of the quality of the substance;

- in the event of differences of opinion, information and data are collected to check whether all European products comply with the requirements in the draft European monograph and to provide a basis for adjusting the specifications and reaching an agreement;
 - if differences of opinion persist after information and data have been collected, when there are non-scientific difficulties or differences in concept, the problem is submitted to the European Pharmacopoeia Commission.
10. When several national methods exist for the same test, the EDQM Laboratory or an expert from the HOM Working Party carries out a comparative study of the methods and submits his or her recommendations, with appropriate arguments and justifications, to the HOM Working Party, which will take its decision based on these recommendations.
 11. If a new test (not part of a national monograph) is proposed, the HOM Working Party discusses the need to include this test in the European draft to guarantee the quality of the substance in Europe based on the scientific data provided by the requestor. Indeed, it is proposed that only tests that are justified because they guarantee the quality of the substance and which are based on scientific data can be introduced into the European draft.
 12. The first draft is then submitted to the Secretariat in one of the official languages; the Secretariat is responsible for translation of the texts into the other official language and for final editorial verification of the texts.

APPROVAL FOR PUBLICATION IN PHARMEUROPA

1. The draft monograph and a report of the laboratory studies carried out are presented to the HOM Working Party. If there are no difficulties, this draft is simultaneously published in Pharmeuropa online and submitted for comment to the National Pharmacopoeia Authorities.
2. If the Working Party considers that further work is required, this should be undertaken by the co-ordinator or the co-worker and, if necessary, the EDQM Laboratory and preferably the results should be presented at the next meeting of the HOM Working Party.
3. In general, the draft to be published in Pharmeuropa online is approved by the HOM Working Party in not more than two meetings.
4. If there are any non-scientific difficulties or differences in conception, the problem is immediately submitted to the Commission.

PUBLICATION IN PHARMEUROPA

1. Once the HOM Working Party has approved the draft monograph, any editorial amendments are made by the Secretariat, and the monograph is published in Pharmeuropa online and simultaneously sent to the National Pharmacopoeia Authorities, industry associations and published on the [EDQM](#) and the [HMA](#) (Heads of Medicines Agencies) web sites.
2. Whenever appropriate, the author of the monograph or the Secretariat prepares an explanatory note to be published at the same time as the monograph. This note contains information that may be useful to the reader, for example, explanations of the modifications made to the national monographs, and where applicable, explanations on the introduction of new tests or the introduction of a transition period.
3. The deadline for comment by the public is set at 3 months from the closing date of Pharmeuropa.

EXAMINATION OF THE COMMENTS

1. The Secretariat uses an electronic “Document Review Tool” (DRT) to prepare the compilation of the comments received which are made available to the co-ordinator/co-worker and to the HOM Working Party for its next meeting.
2. The co-ordinator reviews the comments, tries to resolve any difficulties by carrying out, where relevant, any necessary laboratory work (the EDQM Laboratory may be asked to help), and submits proposals to the Working Party.
3. The HOM Working Party examines the comments received from the national authorities and in the light of these comments decides to:
 - ask the Secretariat to prepare the COM document for submission to the Commission for adoption, in absence of major objection by the National Pharmacopoeial authorities;
 - in cases where important modifications are foreseen in the light of the results of further work or of the public enquiry (change of a method, significant change of specifications), either a second publication is envisaged or National Pharmacopoeia Authorities are consulted;
 - send the monograph to the HOM Working Party for the study of the test for which a fundamental objection had been received. If there are any non-scientific difficulties or differences in conception, the problem is immediately submitted to the Commission.

ADOPTION BY THE COMMISSION

The Secretariat prepares the document for the Commission for adoption at the next Session.